Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effectiveness of metformin in the prevention of preeclampsia in pregnant women at high risk of preeclampsia

Protocol summary

Study aim
Investigating the effectiveness of metformin in preventing preeclampsia in pregnant women

Design
Clinical trial with a control group, with parallel groups, without blinding, randomized, phase 2 on 160 patients. A table of random numbers was used for randomization.

Settings and conduct
This study will be conducted on pregnant mothers aged 18 to 45 who have a risk factor for preeclampsia in 1402 at Isfahan University of Medical Sciences. Blinding was not achieved in this study.

Participants/Inclusion and exclusion criteria
This study will be conducted in Isfahan University of Medical Sciences in 1402 on pregnant mothers who have a risk factor for preeclampsia and do not have any other underlying disease.

Intervention groups
People in the intervention group in this study are treated with metformin 500 daily from the 12th week of pregnancy. The control group does not receive drugs

Main outcome variables
preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230730058975N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
vida Behzad Far

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 913 511 0976

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behzadfar_neda@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of metformin in the prevention of preeclampsia in pregnant women at high risk of preeclampsia

Public title
Metformin in the prevention of preeclampsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age 18 to 45 informed consent having risk factors for preeclampsia

Exclusion criteria:
underlying disease like diabetes

Age

From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done individually and simply. At first, according to the number of samples, random numbers are created with the help of a random number table and placed in each envelope. The envelopes are also numbered in order. According to the order of people entering the study, an envelope is opened and a random number is determined. If the random number is odd, they are placed in the first group and if it is even, they are placed in the second group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-09-07, 1401/06/16

Ethics committee reference number
IR.MUI.MED.REC.1401.223

Health conditions studied

1

Description of health condition studied
preeclampsia

ICD-10 code
O14

ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
preeclampsia

Timepoint
Every two weeks from the 12th week of pregnancy

Method of measurement
history taking and physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Metformin 500 mg tablets, produced by Iran Najo company, one daily from the 12th week of pregnancy

Category
Treatment - Drugs

2

Description
Control group: No action or medicine

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Vida Behzadfar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
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vida Behzadfar
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resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD

no more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available